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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,911	08/10/2000	Badri N. Prasad	6759	6357
25763	7590	11/02/2005	EXAMINER	
DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT 50 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402-1498			BLECK, CAROLYN M	
			ART UNIT	PAPER NUMBER
			3626	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/635,911	Applicant(s) PRASAD ET AL.	
	Examiner Carolyn M. Bleck	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 36-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 and 36-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the response filed 17 August 2005. Claims 1-34 and 36-49 are pending. None of the claims have been amended.

Claim Objections

2. Claim 6 is objected to because of the following informalities: line 2, the phrase "remove correct obviously" appears to be grammatically incorrect. Appropriate correction is requested.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-34 and 36-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The preamble of claim 1 recites "predicting a level of consumption of healthcare resources by modeling utilization of healthcare resources in a target period based on a plurality of provider claims from a base period maintained for a member of a healthcare plan." However, the body of the claim does not recite steps pertaining to predicting a level of consumption of healthcare resources by modeling utilization of healthcare

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resources." Appropriate correction is requested.

6. Claims 2-34 and 36-47 inherit the deficiencies of claim 1, and are therefore rejected for the same reasons as claim 1.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-34, 36, and 39-47 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claimed invention as a whole must accomplish a practical application. That is, it must produce a "useful, concrete and tangible result." *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F. 3d 1368, 73 (Fed. Cir. 1998). The purpose of this requirement is to limit patent protection to inventions that possess a certain level of "real world" value, as opposed to subject matter that represents nothing more than an idea or concept, or is simply a starting point for future investigation or research ((*Brenner v. Manson*, 383 U.S. 519, 528-36 (1966); *In re Ziegler*, 992 F.2d 1197, 1200-03 (Fed. Cir. 1993)). Accordingly, a complete disclosure should contain some indication of the practical application for the claimed invention, i.e., why the applicant believes the claimed invention is useful.

In this case, claim 1 recites the steps of "calculating a burden of illness for the member based on the provider claims," and "computing a score for the member based on the burden of illness and at least one explanatory variable." However, claim 1 does

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not appear to accomplish a practical application or to provide "real world" value. The claim does not recite any steps beyond computing a score. It is unclear what is done with the score once the method is completed (i.e., is it used to predict patients consuming healthcare resources?).

Similar analysis can be applied to claims 2-34, 36, and 39-47. As such, these claims are rejected for the same reasons as claim 1.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-5, 16, 18-24, 27-32, 36-37, 39-47, and 48-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Lash (US 2001/0020229 A1).

(A) As per claim 1, Lash discloses an automated method for predicting the likelihood that a patient will acquire high medical service utilization characteristics, thereby becoming a high-cost patient to a managed care organization relative to other patients, within a given period of time based on a previous time period (Abstract, par. 22) comprising:

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(a) calculating multiple products using variables related to the number of hospital in-patient days for respiratory-related admissions involving ICU care at any time during the admission, the number of hospital in-patient days for respiratory related admissions not involving ICU care at any time during the admission, the number of hospital in-patient days for non-respiratory related admissions, cost of medical services, etc. (see par. 49), wherein the products are calculated by multiplying the variables by the coefficients resulting in multiple products, wherein the variable data is obtained from patient claims (It is noted that these products are considered to be a form of BOI. Applicant has not defined what a BOI is in claim 1 other than to recite that it is a number) (par. 7-10, 21-31, 37, 49-54, 57-60); and

(b) computing a score/probability (see par. 54) for a patient based on the products mentioned in step A, considered to be a burden of illness, and at least one other variable, wherein the scores are computer for each of a plurality of members in a health plan (par. 7-10, 21-31, 37, 41, 49-54, 57-60, claims 1-5).

(B) As per claims 2-4, Lash discloses using pharmacy claims, medical claims, or both (par. 24-25, 59).

(C) As per claim 5, Lash discloses prior to the calculating step, the step of extracting a data set from the plurality of provider claims, the data set including only information from the base period, from the plurality of provider claims relevant to healthcare utilization

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during the target period, and further wherein the calculating step is based on the data set (par. 7, 24-31, 46-54, 57-59).

(D) As per claim 16, Lash discloses that many different claims variables and encounter data (e.g., an ER visit) are available for potential use in the model. the number of hospital in-patient days for respiratory-related admissions involving ICU care at any time during the admission (ICUDAY); the number of hospital in-patient days for respiratory related admissions not involving ICU care at any time during the admission (SPDAY); the number of hospital in-patient days for non-respiratory related admissions (OTHRDAY); whether the patient has had one respiratory related ER visit in the index year (ERRESPC1); whether the patient has two or more respiratory related ER visits in the index year (ERRESPC2); the number of the patient's non-respiratory related ER visits (ER_OTHR); the number of respiratory related office visits of the patient (OV_RESP); the number of non-respiratory related office visits (OV_OTHR); the number of prescription drug claims (RXCNT); *the presence or absence of an allergy-related diagnosis (CMALERG2); the presence or absence of a respiratory infection diagnosis (CMINFEC2); the presence or absence of another respiratory related (comorbid) diagnosis (CNIRSPIR2); the presence or absence of hypertrophied nasal turbinate diagnosis (CMNAST2); and the presence or absence of respiratory complication diagnosis (CONDLIC).* Of course, other claims data and encounter information can also be stored and used in the patient database (par. 49).

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(E) As per claim 18, Lash discloses assigning the pharmacy claims to one of a plurality of groups based on a relationship to corresponding medical claim indicating the presence of the medical episode (see the number of prescription drug claims, the presence or absence of another respiratory related (comorbid disease), the presence or absence of hypertrophied nasal turbinate diagnosis (CMNAST2), and the presence or absence of respiratory complication diagnosis (CONDLIC)) (par. 49-54).

(F) As per claim 19, Lash discloses using medical claims (par. 59).

(G) As per claim 20, Lash discloses multiplying each of the groups representing a medical episode, present for the member, by a predetermined weight factor (see Table 1 and 2 on pg. 6) and summing the products to achieve a single number (see Table 2 – product) (see also par. 49-54).

(H) As per claims 21-24, Lash discloses the weighing coefficients relating to: comorbidity (par. 49), complications (see Complic2 in Table 1), age, and sex (par. 49-54).

(I) As per claims 27-32, Lash discloses the variables pertaining to age, sex, number of chronic claims, such as respiratory claims and non-respiratory claims, the number of ER visits and office visits, the number of prescription drug claims pertaining to a respiratory disease, and the cost of medical services used by a patient in a time period (par. 10, 37, 49-54).

(J) As per claims 36-37, Lash discloses using pharmacy claims and isolating patients having a score above a certain threshold, for example 90% (par. 40-42, 44, 59).

(K) As per claim 39, Lash discloses calibrating the model by comparing the score against the resource utilization for a known target year (par. 60-64).

(L) As per claims 40-42, Lash discloses using pharmacy claims, medical claims, or both (par. 24-25, 59).

(M) As per claim 43, Lash discloses calibrating the model by comparing a score against utilization for a known target period, where the utilization is for asthma related use of services (par. 60-64).

(N) As per claims 44-46, Lash discloses using pharmacy claims, medical claims, or both (par. 24-25, 59).

(O) As per claim 47, Lash discloses calculating multiple products using variables related to the number of hospital in-patient days for respiratory-related admissions involving ICU care at any time during the admission, the number of hospital in-patient days for respiratory related admissions not involving ICU care at any time during the

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admission, the number of hospital in-patient days for non-respiratory related admissions, cost of medical services, etc. (see par. 49), wherein the products are calculated by multiplying the variables by the coefficients resulting in multiple products, wherein the variable data is obtained from patient claims (It is noted that these products are considered to be a form of BOI. Applicant has not defined what a BOI is in claim 1 other than to recite that it is a number) (par. 7-10, 21-31, 37, 49-54, 57-60). These numbers are then calibrated by comparing these variables against resource utilization for a known target year (par. 60-66).

(P) As per claims 48-49, Lash discloses an automated method for predicting the likelihood that a patient will acquire high medical service utilization characteristics, thereby becoming a high-cost patient to a managed care organization relative to other patients, within a given period of time based on a previous time period (Abstract, par. 22) comprising:

(a) collecting patient claims data in electronic form on a population of patients (par. 7, 24, claim 1);

(b) calculating multiple products using variables related to the number of hospital in-patient days for respiratory-related admissions involving ICU care at any time during the admission, the number of hospital in-patient days for respiratory related admissions not involving ICU care at any time during the admission, the number of hospital in-patient days for non-respiratory related admissions, cost of medical services, etc. (see par. 49), wherein the products are calculated by multiplying the variables by the

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coefficients resulting in multiple products, wherein the variable data is obtained from patient claims (It is noted that these products are considered to be a form of BOI.

Applicant has not defined what a BOI is in claim 1 other than to recite that it is a number) (par. 7-10, 21-31, 37, 49-54, 57-60);

(c) computing a score/probability (see par. 54) using multiple (see multivariate, par. 25) regression analysis (par. 27) for a patient based on the products mentioned in step A, considered to be a burden of illness, and at least one other variable, wherein the scores are computer for each of a plurality of members in a health plan (par. 7-10, 21-31, 37, 41, 49-54, 57-60, claims 1-5); and

(d) using the score to predict healthcare resource consumption by the plan member as an effort to prevent the plan member from making excessive use of services (par. 39-42, 49-57).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 6-15 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lash (US 2001/0020229 A1) as applied to claim 1, and further in view of Wong et al. (5,976,082).

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(A) As per claim 6, Lash does not explicitly disclose cleaning the data to remove erroneous information by comparing categories of the data set to acceptable values. Wong discloses cleaning data and performing quality checks by using threshold values to check whether an imbalance exists in the data, whether claims need to be rejected, or if multiple claims exist (col. 3 line 40 to col. 4 line 44, col. 6 lines 32-45, col. 8 lines 23-35). At the time the invention was made, it would have been obvious to include the features of Wong within the method taught by Lash with the motivation of increasing the accuracy of predictions made by a MCO to identify patients who will become or remain high-use patients, thus reducing costs for healthcare (Lash; par. 6).

(B) As per claim 7, Lash does not expressly disclose a step of placing a plurality of pharmacy codes, representing a prescribed medication, into a plurality of therapeutic pharmacy classes. However, Lash does include analyzing pharmacy claims (par. 59). Wong discloses assigning prescribed medications including the drug codes into drug therapeutic classes (Figures 2-5, col. 7 lines 37-47, col. 11 lines 14-68). At the time the invention was made, it would have been obvious to include the features of Wong within the method taught by Lash with the motivation of utilizing a database of claims data and efficiently analyzing the claims data to quickly predict the patients who will utilize medical services (Lash; par. 6, 24).

(C) As per claim 8, Lash and Wong fails to expressly disclose using GC3 therapeutic pharmacy classes. However, Wong discloses assigning prescribed medications

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including the drug codes into drug therapeutic classes, specifically DM therapeutic class codes (Figures 2-5, col. 7 lines 37-47, col. 11 lines 14-68, Appendix III). It is respectfully submitted that the skilled artisan could use another form of classes other than DM class codes as disclosed by Wong. The motivation being to provide a flexible coding system when generating models thus increasing the usefulness of the models.

(D) As per claim 9, Wong discloses multiplying each of the independent variables, such as ischemic heart disease, cardiac dysrhythmias, hypertensive disease, number of co-morbid diseases, number of CHF hospitalizations, number of CHF emergency services, number of physician office visits, number of ACE inhibitor prescriptions, number of digoxin prescriptions (reads on "therapeutic pharmacy classes"), and number of loop diuretic prescriptions, by a parameter estimate and then summing the independent variables times the parameter estimates to calculate a value (reads on "burden of illness") (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33). The motivation for combining Wong within Lash is given above in claim 7, and incorporated herein.

(E) As per claim 10, Wong discloses multiplying each of the independent variables, such as ischemic heart disease, cardiac dysrhythmias, hypertensive disease, number of co-morbid diseases, number of CHF hospitalizations, number of CHF emergency services, number of physician office visits, number of ACE inhibitor prescriptions, number of digoxin prescriptions (reads on "therapeutic pharmacy classes"), and number

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of loop diuretic prescriptions, by a parameter estimate and then summing the independent variables times the parameter estimates to calculate a value (reads on "burden of illness") (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

Lash and Wong fails to expressly disclose summing a plurality of weights corresponding to relevant combinations of therapeutic pharmacy classes present for the member.

However, it is respectfully submitted that when generating models typically the interactions of different variables are examined, and the skilled artisan would have found it an obvious modification to the method of Lash and Wong to include combinations of therapeutic pharmacy classes with the motivation of providing the most accurate model for the prediction of adverse health outcomes (Wong; col. 12 lines 27-31).

(F) As per claims 11 and 14, Wong discloses assigning diseases having ICD-9 codes into a plurality of sub classes (col. 9 line 45 to col. 10 line 31) and summing the independent variables or values for the sub classes multiplied by the parameter estimates to calculate a value (reads on "burden of illness") (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

(G) As per claims 12-13, Wong discloses using ICD-9 codes and therapeutic classes to assign diseases into appropriate subclasses (col. 6 lines 17-32, col. 9 lines 43-63). Although Wong fails to expressly recite CCG classes or categories, it is respectfully submitted that the skilled artisan could use another form of classes other than ICD-9

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class codes as disclosed by Wong. The motivation being to provide a flexible coding system when generating models thus increasing the usefulness of the models.

(H) As per claim 15, Wong discloses the parameter estimates including the total costs, in-patient hospital costs, emergency room costs, doctor costs, cardiovascular costs, and CHF costs, wherein the costs are associated with an ICD-9 code (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33).

(I) As per claims 25-26, Lash discloses using data pertaining to the cost of medical services for each patient in the previous time period (par. 37). However, Lash does not include the predetermined weight factor being based on an average incremental cost associated with a group or with a group for a benchmark population. Wong discloses a parameter estimate relating to the cost of in-patient hospital costs, emergency room costs, doctor costs, and pharmacy costs (col. 12 line 46 to col. 13 line 50, col. 14 line 49 to col. 15 line 33). At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Wong within the method of Lash with the motivation of accurately predicting which patients will be the greatest utilizers of medical resources (Lash; par. 5-6).

13. Claims 17 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lash (US 2001/0020229 A1) as applied to claim 1.

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(A) As per claim 17, Lash fails to expressly disclose Clinical Care Groups. However, Lash discloses placing the plurality of claims data into groups based on a medical episode (see par. 49). It is respectfully submitted that using a specific grouping (i.e. Clinical Care Groups) is another form of grouping. The skilled artisan would have it obvious to include another grouping schema within the method of Lash. The motivation being to provide a flexible grouping system when generating models thus increasing the usefulness of the models.

(B) As per claim 38, Lash discloses using medical claims and pharmacy claims (par. 59). Although Lash does not expressly disclose calculating a second score based on information in both the pharmacy claims and the medical claims, it is respectfully submitted that using both sets of claims would have been an obvious modification to Lash with the motivation of ensuring the accuracy of the model. (See Lash's discussion of calibrating the model to predict the true, high service use population by using "goodness-of-fit testing" to determine whether the model is good. Data from a second database is inserted into the model to determine whether it is a good fit (par. 61)).

14. Claims 33-34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lash (US 2001/0020229) as applied to claim 1, and further in view of Lockwood (5,706,441).

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(A) As per claims 33-34, the teachings of Lash in the rejections above are incorporated herein.

Lash discloses calculating a probability that a patient will be a high use patient of medical resources in the following year, wherein the score/probability is scaled to run from 0 to 100, with the higher number meaning a greater probability that the patient will become high-cost (par. 41, 49-56). Lash does not expressly disclose the step of dividing the score by an average score for the group or by an average score for a benchmark group.

Lockwood discloses comparing the severity scores for sickness episodes against benchmarks by dividing the scores with the benchmarks and comparing a score by the average score for a group (col. 11 line 44 to col. 13 line 41).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to combine the teachings of Lockwood within the method of Lash with the motivation of identifying and assessing high risk patients (par. 41, 49-56).

Response to Arguments

15. Applicant's arguments with respect to claims 1-34 and 36-49 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (571) 272-

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6767. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (571) 272-6776.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

17. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(571) 273-8300	[Official communications]
(571) 273-8300	[After Final communications labeled "Box AF"]
(571) 273-6767	[Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"]


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Hand-delivered responses should be brought to the Knox Building, Alexandria, VA.

CB

CB

October 26, 2005


JOSEPH THOMAS
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